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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SYED F.A. HOSSAINY,
FUH-WEI TANG, LOTHAR W. KLEINER, THIERRY GLAUSER,
YIWEN TANG, WOUTER E. ROORDA, STEPHEN D. PACETTI,
GINA ZHANG, YUNG-MING CHEN, ANDREW F. MCNIVEN,
SEAN A. MCNIVEN, and BRANDON J. YOE

Appeal 2016-002125
Application 13/953,656[1]
Technology Center 1600

Before FRANCISCO C. PRATS, JOHN G. NEW, and
DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134(a) involves claims to a process in which pressure greater than ambient pressure is applied to a medical device with a polymer coating. The Examiner rejected the claims for obviousness.

We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

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[1] Appellants identify Abbott Cardiovascular Systems Inc., as the real party in interest. App. Br. 3.

STATEMENT OF THE CASE

The following rejections have been entered and maintained by the Examiner:

(1) Claims 1–3, 5, 12, 16, 17, 21, and 22, rejected under 35 U.S.C. § 103(a) as unpatentable over Pacetti '462[2] and DesNoyer[3] (Final Act. 5–9; Ans. 3);

(2) Claims 1–3, 5, 12, 16, 17, 21, and 22, rejected for obviousness-type double patenting over claims 1–3, 8, and 10 of Pacetti '462 (Final Act. 2–4; Ans. 3); and

(3) Claims 1–3, 5, 12, 16, 17, 21, and 22, rejected for obviousness-type double patenting over claims 1–3, 8, and 10 of Pacetti '391[4] (Final Act. 4; Ans. 3)

Claims 1 and 21, the sole independent claims on appeal, are representative and read as follows (App. Br. 15, 18 (emphasis added)):

> 1. A method comprising:
>
> obtaining a medical device with a polymeric coating layer, *the polymeric coating layer having been dried*;
>
> applying a pressure greater than ambient to the dried polymeric layer of the medical device using a pressure vessel; and
>
> optionally applying heat to the dried polymeric layer of the medical device in combination with the application of the pressure.

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[2] US 6,743,462 B1 (issued June 1, 2004).
[3] US 2005/0288481 A1 (published Dec. 29, 2005).
[4] US 7,335,391 B1 (issued Feb. 26, 2008).

> 21. A method comprising:
>
> obtaining a medical device with a polymeric coating layer, *the polymeric coating layer having been dried*;
>
> applying a pressure greater than ambient to the dried polymeric layer of the medical device using a pressure vessel, the pressure sufficient to create a mechanical deformation of the polymeric layer of the medical device; and
>
> optionally applying heat to the dried polymeric layer of the medical device in combination with the application of the pressure.

OBVIOUSNESS

The Examiner's Prima Facie Case

The Examiner found that Pacetti '462 discloses a process that differs from the rejected claims in that Pacetti '462 dries and pressurizes the polymer coating on its device simultaneously, whereas Appellants' independent claims 1 and 21 require the polymer coating on the medical device to first be dried, after which pressure is applied to the coating. Final Act. 6–7. The Examiner contends, however, that

> absent evidence of criticality, it would have been obvious to dry the polymeric coating layer before application of pressure in view of MPEP 2144.04 which discloses[] "*Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render *prima facie* obvious claims directed to a process of making a laminated sheet by reversing the order of the prior an process steps.). See also *In re*[]*Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re*[]*Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930)."

Final Act. 7 (underlining emphasis by Examiner).

The Examiner cited DesNoyer to show the obviousness of pulsed pressure application, recited in certain dependent claims. Final Act. 7–8.

Analysis

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .
>
> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

Appellants persuade us that the Examiner's conclusion of obviousness is not supported by a preponderance of the evidence.

Although the Supreme Court has emphasized "an expansive and flexible approach" to the obviousness question, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), the Court also has reaffirmed the importance of determining "whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue." *Id.* at 418 (emphasis added).

Thus, as our reviewing court has explained, "section 103 requires a fact-intensive comparison of the claimed process with the prior art rather than the mechanical application of one or another *per se* rule." *In re Ochiai*, 71 F.3d 1565, 1571 (Fed. Cir. 1995); *see also id.* at 1572 ("[R]eliance on *per se* rules of obviousness is legally incorrect and must cease.").

Ultimately, therefore, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of

ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

In the present case, as seen above, independent claims 1 and 21 both require obtaining a medical device with a dried polymeric coating, and then applying a pressure greater than ambient to the dried polymeric coating. App. Br. 15, 18.

In contrast, Pacetti '462 discloses that pressure greater than ambient should be applied while the coating is drying, that is, *before* the polymeric coating has dried:

> For a solvent having a high vapor pressure (e.g., above 30 torr at the temperature of application), or in other words volatile solvents, the solvent evaporates extremely rapidly from the composition, leading to difficulties in the application of the composition to the stent. Application of such compositions often lead to coatings having powdered consistency and poor adhesion of the coating to the surface of the stent. *Increasing the pressure in pressure chamber* ***10*** *above ambient pressure causes the solvent to evaporate more slowly leading to a coating with a smoother surface, more uniform composition, and better adhesion.*

Pacetti '462, 4:20–30 (emphasis).

Thus, as is evident, Pacetti '462's reason for increasing the pressure while the polymer coating is drying is to slow solvent evaporation, thereby improving the properties of the resulting dried coating. As is also evident, applying pressure after the polymer has dried as recited in claims 1 and 21, that is, after the solvent has already evaporated, would not slow solvent evaporation and, therefore, would not yield the improvement in the coating process taught in Pacetti '462. Accordingly, because applying pressure to the coating after the coating has dried would negate Pacetti '462's entire

reason for applying pressure, the Examiner does not persuade us that Pacetti '462, even when viewed in light of DesNoyer, would have suggested the process recited in Appellants' claims 1 and 21. We, therefore, reverse the Examiner's rejection of those claims, and their dependents, over Pacetti '462 and DesNoyer.

We acknowledge the Examiner's reliance on MPEP § 2144.04. *See* Ans. 4. Nevertheless, we see nothing in that section or the cases cited therein requiring us, based solely on an alleged *per se* rule, to hold obvious a process claim when the Examiner has advanced no specific evidence, based either on the prior art or an ordinary artisan's general knowledge, suggesting the particular order of steps required by the claim.

To the contrary, as noted above, our reviewing court has expressly explained to the PTO that "reliance on *per se* rules of obviousness is legally incorrect and must cease." *In re Ochiai*, 71 F.3d at 1572; *see also id.* at 1571 ("[S]ection 103 requires a fact-intensive comparison of the claimed process with the prior art rather than the mechanical application of one or another *per se* rule.").

In sum, for the reasons discussed, we reverse the Examiner's rejection of claims 1 and 21, and their dependents, over Pacetti '462 and DesNoyer.

DOUBLE PATENTING

In rejecting Appellants' claims 1–3, 5, 12, 16, 17, 21, and 22 for obviousness-type double patenting over claims 1–3, 8, and 10 of Pacetti '462, the Examiner contends that the rejected claims and allegedly conflicting claims of Pacetti '462 recite "common subject matter as follows: applying greater than ambient pressure to a polymer coating layer on the

surface of a medical device, wherein the polymer can comprise poly D,L lactide and wherein the active ingredients include anti-proliferative agents." Final Act. 4.

In rejecting Appellants' claims 1–3, 5, 12, 16, 17, 21, and 22 for obviousness-type double patenting over claims 1–3, 8, and 10 of Pacetti '391, the Examiner similarly finds that the allegedly conflicting claims of Pacetti '391 recite "common subject matter" with the rejected claims. Final Act. 4.

We reverse these rejections as well. As the Examiner concedes (Ans. 9), claim 1 of Pacetti '462 recites a process in which greater than ambient pressure is applied while the polymer coating is being placed on the medical device, rather than after the coating is dried, as required by Appellants' claims 1 and 21. *See* Pacetti '462, 7:14–28 (solvent-containing composition applied to medical device while device is disposed in pressurized environment (step (c)).

Claim 1 of Pacetti '391 similarly recites pressurizing before and during coating, rather than after the coating is dried. *See* Pacetti '391, 7:21–31 (adjusting pressure is "followed by" applying coating to medical device).

Thus, contrary to the Examiner's assertion, because the rejected claims recite a different order of steps than the order recited in the allegedly conflicting claims of Pacetti '462 and '391, the rejected claims do not recite "common subject matter" with the claims of Pacetti '462 and '391.

In addition, the Examiner does not advance evidence explaining why an ordinary artisan would have considered it obvious to modify the processes recited in the claims of Pacetti '462 and '391 to arrive at a process having the order of steps required by the rejected claims. Rather, the

Examiner again bases the conclusion of obviousness on MPEP § 2144.04. Ans. 9.

Essentially for the reasons discussed above as to the Examiner's obviousness rejection, we are not persuaded that the Examiner has explained adequately why the process recited in the rejected claims would have been obvious over the claims of Pacetti '462 and '391. We, therefore, reverse both of the Examiner's rejections for obviousness-type double patenting.

SUMMARY

We reverse each of the Examiner's rejections.

REVERSED